

Revision: HCFA-PM-87-4 (BERC)
March 1987

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State/Territory: North Carolina

Standards for the Coverage of Transplant Services

A. Organs

Medically necessary organ transplants are covered. At present types of transplants which are in this category include kidney, heart, heart-lung(s), liver, corneal, skin tendon, bone and bone marrow.

Major organ transplantations, which include liver, heart, heart-lung(s), and bone marrow are covered for eligible recipients. Prior approval is required. Documentation for coverage is reviewed on a case by case basis. In applying these standards (see individual policies), similarly situated individuals will be treated alike.

The documentation required with the request for coverage should include the following information:

- A recent medical summary of the patient's clinical course
- Age of patient
- Diagnosis
- Onset of illness
- Failure of other forms of therapy
- Cost of preoperative workup and what it entails
- Estimated cost of surgical procedure and what it entails
- Institution where the transplant is to be performed
- Estimated length of hospital stay
- Estimated dosage, duration and cost of immunosuppressive therapy

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1. Liver Transplantation

Liver transplantation is a promising alternative to current therapy in managing the late phase of several serious liver diseases. Candidates include children and adults suffering from irreversible liver injury who have exhausted alternative medical and surgical treatments and are approaching the terminal phase of their illness.

Coverage is extended to the following conditions:

- Extrahepatic and intrahepatic biliary atresia (patients who fail to respond to hepatoenterostomy, kasai procedure)
- Chronic active hepatitis (exception, dry-induced chronic active hepatitis, which usually responds to removal of the chemical agent, and hepatitis B - induced disease, in which viremia persists)
- Primary biliary cirrhosis
- Hepatic based inborn errors of metabolism
- Hepatic vein thrombosis (Budd-Chiari Syndrome). Patients who have not responded to anticoagulation or appropriate surgery for portal decompression may be candidates.
- Sclerosing Cholangitis
- Primary hepatic malignancy (confined to the liver, but not amenable to resection)
- Other disorders will be considered on an individual basis.

Prior approval is required. Documentation required with prior approval request includes:

- A recent medical summary of the patient's clinical course;
- Age of patient;
- Diagnosis;
- Date of onset of illness;
- Failure of other forms of therapy, including previous transplantations;
 - a. Type;
 - b. Duration;

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- . Cost of preoperative workup and what it entails;
- . Estimated cost of operation and what it entails;
- . Institution where transplant is to be performed;
- . Estimated length of hospital stay;
- . Estimated dosage, duration, and cost of immunosuppressive therapy.

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2. Heart Transplantation

Cardiac transplantation is reserved for those suffering from end-stage cardiomyopathies with a prognosis for survival of less than 12 months.

The following indications and contraindications for heart transplantation are to be used simply as an indicator if a respectable survival rate is to be attained. They are not intended to be used as strict guidelines.

Indications:

End-stage cardiomyopathy prognosis
Less than 12 month survival

Absolute Contraindications:

Active infection
Pulmonary vascular resistance >8 Wood units
Insulin requiring diabetes mellitus
Life-limiting condition, such as:
 Cachexia with hepatomegaly and ascites
 Severe chronic obstructive pulmonary disease
 Severe peptic ulcer disease malignancy
Drug addiction
Psychosis

Relative Contraindications:

Psychosocial instability

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3. Combined Heart-Lung Transplantation

Combined heart-lung transplantation is now covered for end-stage parenchymal or vascular pulmonary diseases. These can be broadly divided into those patients who have damage of both the heart and lungs, or those who have irreversible pulmonary failure alone.

The first category comprises patients with advanced pulmonary vascular disease - either Eisenmenger's Syndrome or primary pulmonary hypertension.

The second category of potential recipients for combined heart-lung transplantation consists of those with irreversible disease of both lungs without significant cardiac involvement. Included here are patients who have severe chronic obstructive airways disease, pulmonary fibrosis, cystic fibrosis and other enzyme deficiencies.

Prior approval is required. Documentation required with prior approval request includes:

- A recent medical summary of the patient's clinical course;
- Age of patient;
- Diagnosis;
- Date of onset of illness;
- Failure of other forms of therapy, including previous transplantation;
 - a. Type;
 - b. Duration;
- Cost of preoperative workup and what it entails;
- Estimated cost of operation and what it entails;
- Institution where transplant is to be performed;
- Estimated length of hospital stay;
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4. Heart Transplantation on Medicare Eligible Medicaid Beneficiaries

Medicare has recently approved heart transplantation (HT) for Medicare eligible persons. HCFA has further stipulated that HT for Medicare eligible beneficiaries must be performed at HCFA designated Medicare Heart Transplant Centers. Currently, sixteen (16) such centers have been designated. The nearest is the University of Virginia Medical Center in Richmond.

In keeping with long-standing policy concerning persons eligible for both Medicare and Medicaid, the N.C. Medicaid program pays the Medicare deductible and coinsurance and the Part B premiums.

Since Medicare does cover HT, Medicare and/or Medicaid eligible persons requiring HT will be encouraged to obtain HTs at designated centers.

The N.C. Medicaid program will consider covering HT for persons in the following four circumstances:

- Emergency situations. This not only includes life saving situations in rapidly deteriorating patients but, also, the availability of a donor heart that might otherwise be lost if not transplanted within a certain time period into a suitable recipient;
- Patients in need of HT but too ill to be considered for transportation to a remote facility for evaluation and transplantation;
- Patients who are turned down by HCFA designated centers for reasons other than medical necessity (for example, when the designated center cannot accommodate additional patient(s) because of current workload levels). Providers requesting coverage by Medicaid in such cases should obtain a denial in writing from at least one designated center and include it in their request for prior approval.
- If the state determines it is medically necessary to provide the HT in other than a Medicare certified center.

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5. Lung(s) Transplantation

Single and double lung transplantations are promising therapies for selected patients with lung diseases such as: Chronic Obstructive Lung Disease, Idiopathic Pulmonary Fibrosis, Cystic Fibrosis, Pulmonary Hypertension with no evidence of severe right ventricular failure, Alpha-1 Antitrypsin Deficiency, etc. It is reserved for end-stage lung disease with evidence of progression and a life expectancy of less than 18 months.

Selection criteria for lung transplant recipients include:

- Absence of other significant systemic disease;
- Absence of significant coronary artery disease;
- Absence of evidence of right ventricular (RV) failure (tricuspid regurgitation, ascites, hepatomegaly, poor RV contractibility);
- Demonstrated compliance with medical regimens;
- Psychosocial stability: no history of psychosis
or alcohol/drug abuse;
- Mobility - must be ambulatory with oxygen as required;
- Must NOT be on systemic steroids;
- For single lung transplantation:
 - absence of chronic infectious lung disease (e.g. chronic bronchitis; bronchiectasis, cystic fibrosis);
- For double lung transplantation:
 - no prior major thoracic surgery or pleurodesis.

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6. Organ Transplant Center Criteria

Restrictive criteria on facilities or practitioners which provide the organ transplants described will be consistent with the accessibility of high quality care to individuals eligible for the procedures.

The staff must be well trained and have experience in organ transplantation surgery.

The facility must have both the expertise and the commitment for participation in medical, surgical, and other relevant areas including anesthesia, infectious disease, nursing, pathology, social services, immunology, pediatrics, psychiatry, radiology, etc.

7. Immunosuppressive Therapy

Cyclosporin and other immunosuppressive agents are covered for transplantation recipients. No additional program limitations over the existing prior approval requirements for transplants are necessary.

B. Other Transplants

Coverage for other required transplants excluding bone, skin, corneal, kidney and autologous tendons require prior approval. Prior approval is based on medical necessity and state's medical policy.

C. Bone Marrow

Prior approval may be granted for bone marrow transplants for patients with:

1. Aplastic anemia;
2. Acute lymphocytic leukemia;
3. Chronic non-lymphocytic leukemia;
4. Acute myelogenous (granulocytic) leukemia;
5. Other conditions after in-house physician review and consultation.

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Donor Fees

Donor fees must be allowed in all cases for which prior approval is given. Billing for the fees will be made in a lump sum on the hospital inpatient claim. This procedure is consistent with current billing procedures for other transplants.

EPSDT

The EPSDT transplant coverage will be available to all EPSDT recipients if the state determines the services are medically necessary.

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